

SURGICAL INTRAMEDULLARY IMPLANT WITH IMPROVED LOCKING FOR  
FIXATION OF FRACTURED BONE SEGMENTS

Technical Field

**[0001]** The present invention relates to surgical intramedullary implants for setting bone fractures, and more particularly to a surgical intramedullary implant with improved locking for fixation of fractured bone segments.

Background of the Invention

**[0002]** The conventional method of intramedullary nailing of a fractured or broken femur, as shown in Figure 1A, requires first placing the patient 100 on the fracture table 110 for the surgical treatment e.g., intramedullary nailing of a left femur. The patient is shown to be in a supine position, that is, lying on his/her back. The feet are placed in a traction device 120 which holds the femur stretched out to length. In the majority of cases, this will be sufficient to allow the surgical procedure to proceed. Figure 1B shows a frontal projection of the patient 100 in the supine position.

**[0003]** The position of the broken fragments is monitored by an x-ray machine called a "fluoroscopy machine" (not shown) which provides real-time x-ray images to the surgeon. It will be recognized that some surgeons would prefer that the patient be placed on the side with the injured extremity extending upwards. Figure 1C shows a posterior projection of a patient 100 placed in the lateral position, with the patient 100 on his/her side. Figure 1D

shows a frontal projection of the patient 100 on the fracture table 110 in the lateral position, with the fractured side upwards.

**[0004]** Referring to Figures 2A-2F, after the location of the incision in the applicable thigh and femur is prepared by cleansing and sterilizing, an incision 200 is made over the proximal end 212 of the femur 210 in the area that will be referred to as the "greater trochanter" 214. Figure 2A depicts an incision 200, with the normal dissection performed on the area of the trochanter 214 and the neck 216 of the femur 210, which is the broken bone in the present example. Proper retraction is made with the tracking table 110 and the startable area is identified. This is just medial to the greater trochanter 214 described above.

**[0005]** A starter hole 202 can be made using either of two procedures. An awl 220, as shown in Figure 2B, or a guide wire with a sharp end (not shown) is used to make the starter hole. Figures 2B' and 2B'' depict different views of the awl 220 as it makes the starter hole.

**[0006]** Once the starter hole is made, reaming using reamer 230 is begun. Reaming is usually performed over a guide wire. In some cases, if the traction described earlier does not place the broken fragments in the proper alignment and reduction, a procedure can be performed, after partial reaming from the proximal end 212, across the fracture 219, to the distal end 218 of the main proximal fragment, to insert a short internal fracture alignment

device (not shown) or short intermedular rod (not shown) to improve the alignment reduction. The reaming at different stages is shown in Figures 2C and 2D.

**[0007]** Once the fracture is sufficiently reduced and aligned, with proper length restoration attained to the satisfaction of the surgeon, a guide wire 240 with a ball tip 242 is inserted with a hammer (not shown). The guide wire 240 is pushed down through the intermedular area to the distal end 218 of the femur 210. That is, the guide wire 240 is pushed into the distal fragment. Usually the guide wire 240 will stop at a desired area, such as the old epiphyseal line or just proximal to the kneecap in the present example. The positions of the guide wire 240 are monitored using the fluoroscopy machine as described above. Figure 2E depicts the termination of the ball tip guide wire 240. It will be noted that the guide wire 240 has calibrations 244 to show how deep the wire has been inserted. This enables the surgeon to choose the appropriate length of the nail. Alternatively, as shown in Figure 2E, the determination of nail length can be made by using a metal ruler 246 strapped to the skin. With the ruler 246, the necessary depth and the necessary length of the nail are determined using the fluoroscopy machine.

**[0008]** Figure 2F depicts the reaming process over an already implanted ball tipped guide wire 240. The reaming with the reamer 230 proceeds up to the desired diameter of the nail. For each individual patient there are limitations on the reamed diameter due to the constraints of the cortical surfaces. The determination of precisely how much reaming to do is made by the surgeon on a case-by-case basis.

DOCKET NO: 3023-005  
FILE NO: 1228.42361X00  
CLIENT REF: JIGLESS NAIL

**[0009]** Referring now to the images in Figures 3A and 3B, after the reaming of the intermedullary cavity of both fragments, i.e. the bone on both sides of the fracture 219, the proximal fragment 212 which broke and the distal fragment 218 of the femur 210 remain aligned and traversed by a ball tipped guide wire 240. A plastic sleeve (not shown) is inserted into the reamed cavity over the ball tipped guide wire 240. This allows removal of the guide wire 240 while still maintaining the alignment and reduction attained in the previous steps. Another guide wire 300 is inserted through the plastic sleeve. This latter guide wire 300 does not have a ball tip at the end, and is therefore easily removable after insertion of a nail into the reamed cavity.

**[0010]** Figure 3A depicts the initial insertion of the nail 310 into the reamed cavity. Figure 3B shows the nail 310 being inserted with an attached handle 322 and jig 320 to allow hammering of the nail 310 to its proper depth with a hammer or slaphammer (as shown). Attached to the jig 320 in Figure 3B is an angle guide 324. After the nail 310 is seated, the angle guide 324 is used to prepare the nail for a locking screw or screws.

**[0011]** Referring now to Figures 4A and 4B, the jig 320 is shown in place, with the hammer or slaphammer removed. As shown in Figure 4A, a drill 400 is aligned by the jig 320 to be at a predetermined angle in order to ensure that the drill bit 402 will be directed through the predrilled holes in the nail 310 and will exit at the lesser trochanter 213, which is the smaller prominence on the opposite side of the bone from the greater trochanter 214. As shown in Figure 4B, after drilling, a depth gauge 410 is used to select the proper length

of the locking screw. At this point it should be noted that in some fractures of the femur 210, the surgeon may decide that the locking screw should go essentially from the greater trochanter area 214 through the predrilled hole in the nail 310, and be fixed firmly into the lesser trochanter 213. On the other hand, the surgeon may decide that, because of the fracture, a different type jig (not shown) will be used to allow insertion of a screw or screws into the femoral neck 216 and head of the femur 210. The choice is made by the surgeon on a case-by-case basis.

**[0012]** It should also be noted that, in many cases, it is considered necessary to secure the reduction obtained by the traction described above, both proximal and distal locking screws are necessary. Using a jig 500, such as that shown in Figures 5A and 5A', to secure distal locking of the nail 310, which typically has two holes in its distal portion, has not been very successful in practice. Variations in position of a millimeter or more can make it very difficult to insert distal locking screws.

**[0013]** This is because the surgeon must place the screws through an incision similar to the proximal incision described above, up through cortical bone, and into the predrilled holes in the metal intermedullary nail 310. A misalignment of a millimeter or so will make it impossible to advance the screws through the near cortex and both cortices of the nail 310, and to be secured in a far cortex. Therefore, in practice, distal locking jigs 500 have generally been abandoned because of the great difficulty experienced in successfully in placing distal locking screws using a jig technique.

[0014] Instead, the freehand technique is commonly used by surgeons today. The freehand technique requires a sharp tipped awl 500 or a sharp tipped guide wire (not shown). A fluoroscopy machine 520 is also used in this technique. Using this technique, the surgeon must place his/her hand in the field of radiation emitted by the fluoroscopy, i.e. x-ray, machine. In accordance with this technique, the fluoroscopy machine 520 is moved so that the distal holes 312 in the nail 310 perfect circles in the fluoroscopy image, as shown in Figure 5C. Once these perfect circles are obtained, the distal end of the awl 510 or the sharp tipped rigid guide wire is aligned perfectly with this round hole. This must be done twice, since it is generally recommended that at least two distal locking screws of appropriate size be placed to fix the distal portion of the nail 310 to the femur 210. This is very difficult to do and exposes the surgeon, who may be required to perform the freehand technique a number of times each month or year, to dangerous levels of radiation.

[0015] Figure 5B depicts the maneuvering required in the freehand technique to try to place the tip of the awl 510 in the perfectly circular holes. Once the surgeon considers the awl 510 to be properly positioned, a starting hole is made by the awl to start the hole in the near cortex 215 of the femur 210. After this is completed, and the image of the hole remains a perfect circle, i.e. the hole 312 stays where it is supposed to be according to the fluoroscopy machine 520, a power drill is used to make the hole through the near cortex, so as to be perfectly aligned with the hole 312 in the nail 310. The drilled hole extends from the near side of the nail 310 to the far side of the nail, and then finally into the far side of the cortex. If this is successful, a depth gauge is used to determine the proper screw

length and then the screw is placed, as the drill was, across the near cortex of the femur 210, the near cortex of the nail, the far cortex of the nail 310 and the far cortex of the femur.

**[0016]** Needless to say, the fluoroscopy machine 520 has to stay positioned throughout the procedure, because even after drilling it can be difficult to find the weight bearing drilled nail hole 312. As noted above, this procedure must be repeated to allow placement of two or more screws. The femur 210 will take four to eight months to heal, before weight bearing is allowed. In the vast majority of the cases, if only one distal screw is used it will break, making the bone more susceptible to infection and making removal of the screw fragments almost impossible.

**[0017]** Figures 5C and 5C' demonstrate the use of the fluoroscopy machine 520 to show the difference in the profile of the predrilled holes 312 in the distal nail 310. A non-circular hole is shown in Figure 5C' and a perfectly circular hole is shown in Figure 5C.

#### Objectives of the Invention

**[0018]** It is an objective of the present invention to simplify the fixation of fractured bone segments.

**[0019]** Additional objects, advantages, novel features of the present invention will become apparent to those skilled in the art from this disclosure, including the following

detailed description, as well as by practice of the invention. While the invention is described below with reference to preferred embodiment(s), it should be understood that the invention is not limited thereto. Those of ordinary skill in the art having access to the teachings herein will recognize additional implementations, modifications, and embodiments, as well as other fields of use, which are within the scope of the invention as disclosed and claimed herein and with respect to which the invention could be of significant utility.

#### Summary Disclosure of the Invention

**[0020]** An intramedullary nail for insertion into a cavity formed in a fractured bone, such as a femur, includes a proximal portion having first and second opposed ends and a distal portion. A cylindrically shaped, tubular shaft portion of the nail extends between the second end of the proximal portion and the distal portion of the nail.

**[0021]** The proximal portion of the nail has a cylindrically shaped, tubular body extending between the first and second ends along a curved longitudinal axis. An end plate is attached to the cylindrically shaped, tubular body at the first end of the proximal portion of the nail.

**[0022]** According to an aspect of the invention, an opening, which may also be referred to as an aperture, formed at one end of the cylindrically shaped, tubular body by its inner periphery, e.g. its inner circumference, is closed by the end plate. For example, the end

DOCKET NO: 3023-005  
FILE NO: 1228.42361X00  
CLIENT REF: JIGLESS NAIL

plate may serve as a cap plate which more or less seals the end of the cylindrically shaped, tubular body of the proximal portion of the nail.

**[0023]** Beneficially, the end plate includes a first, preferably threaded, screw hole and the cylindrically shaped, tubular body includes a corresponding second, also preferably threaded, screw hole. With the intramedullary nail fully inserted into the fractured bone cavity, the screw hole in the end plate should be visible to the naked eye of the surgeon, thereby facilitating insertion of the locking screw without the use of a jig.

**[0024]** The first and second screw holes are aligned so that a locking screw inserted into the first screw hole is directed through the second screw hole and into a fragment of the fractured bone. For example, if the fractured bone is a femur, the bone fragment into which the locking screw is directed is preferably the greater trochanter or the lesser trochanter. If the screw holes are threaded, the locking screw will engage the holes during insertion.

**[0025]** Advantageously, the cylindrically shaped, tubular body has one diameter near the first end of the proximal portion of the nail and a smaller diameter near the second end of the proximal portion of the nail. The cylindrically shaped, tubular shaft portion may also or alternatively have a smaller diameter than the diameter of the tubular body near the first end of the proximal portion of the nail.

**[0026]** In accordance with yet another aspect of the invention, the proximal portion of the nail is attachable to and removable from the cylindrically shaped, tubular shaft portion of the nail. For example, by providing the cylindrically shaped, tubular body with a first threaded portion at the second end of the proximal portion of the nail, and the cylindrically shaped, tubular shaft portion with a correspondingly second threaded portion, the first and second threaded portions can be engaged to attach the tubular body of the proximal portion of the nail to the tubular shaft portion of the nail.

**[0027]** According to still other aspects of the invention, the longitudinal axis of the cylindrically shaped, tubular body of the proximal portion of the nail is curved in a first plane and in a second plane, which intersects the first plane. The cylindrically shaped, tubular shaft portion of the nail also has a longitudinal axis. Preferably, the longitudinal axis of the cylindrically shaped, tubular body of the proximal portion of the nail is curved in the first plane at an angle in the range of approximately 20° to 25° from the longitudinal axis of the cylindrically shaped, tubular shaft portion of the nail. Furthermore, the longitudinal axis of the cylindrically shaped, tubular body is also curved in the second plane at an angle in the range of approximately 5° to 7° from the longitudinal axis of the cylindrically shaped, tubular shaft portion of the nail.

**[0028]** Preferably, the distal portion of the nail has a cylindrically shaped, tubular body, extending from the cylindrically shaped, tubular shaft portion of the nail. The diameter of the cylindrically shaped, tubular shaft portion of the nail will also preferably be smaller than

the diameter of the cylindrically shaped, tubular body of the distal portion of the nail.

**[0029]** The cylindrically shaped, tubular body of the distal portion of the nail will also typically include a first, preferably threaded, screw hole and a corresponding second, preferably threaded, screw hole. A locking screw is inserted into the first screw hole, through the second screw hole, and into a fragment of the fractured bone.

**[0030]** The locking screws will normally have a head portion and a shaft portion. Beneficially, the shaft portion of each locking screw will have a diameter of no less than 7 mm, which is beneficial in facilitating engagement of the locking screw in the screw hole and into a fragment of the fractured bone by the surgeon, without the need of a jig.

**[0031]** According to another aspect of the invention, each locking screw has a hollow core with threads formed on the outer periphery of the core. A solid cylindrical screw insert is inserted by the surgeon into the hollow core, after insertion of the locking screw. The screw insert is inserted such that it engages the threads within the hollow core. When fully inserted, the screw insert will be disposed within the hollow core.

#### Brief Description of Drawings

**[0032]** Figure 1A depicts a side view of a conventional fracture table and traction device.

**[0033]** Figure 1B depicts a frontal view of the fracture table and traction device of Figure 1A.

**[0034]** Figure 1C depicts another side view of the fracture table and traction device of Figure 1A.

**[0035]** Figure 1D presents another frontal view of the fracture table and traction device of Figure 1A.

**[0036]** Figure 2A depicts an incision being made at the proximal end of a fractured femur.

**[0037]** Figure 2B depicts a starter hole being made in the fractured femur using an awl.

**[0038]** Figure 2B' is a further depiction of the awl of Figure 2B forming the starter hole.

**[0039]** Figure 2B'' depicts a different view of the formation of the starter hole as shown in Figure 2B'.

**[0040]** Figure 2C depicts the reaming from the proximal end of the femur using a reamer.

**[0041]** Figure 2D depicts the reamer of Figure 2C fully extended to the end of the reamed cavity in the femur.

**[0042]** Figure 2E depicts the insertion of a ball tipped guide wire within the reamed cavity of the femur.

**[0043]** Figure 2E' depicts a non-calibrated ball tipped guide wire inserted into the reamed cavity of the femur with a measuring device to determine the length of the nail.

**[0044]** Figure 2F depicts the ball tipped guide wire positioned to allow further reaming to the desired diameter of the nail.

- [0045] Figure 3A depicts the beginning of the insertion of the nail into the reamed cavity.
- [0046] Figure 3B depicts the use of a jig and hammer to insert the nail into the reamed cavity.
- [0047] Figure 4A depicts the conventional drilling of the femur for insertion of the locking screws using the jig depicted in Figure 3B.
- [0048] Figure 4B depicts the measuring of the drilled hole for selection of the proper screw length using a depth gauge.
- [0049] Figure 5A depicts a jig conventionally utilized to set distal locking screws in a femur.
- [0050] Figure 5A' depicts another view of the jig of Figure 5A.
- [0051] Figure 5B depicts convention freehand setting of distal locking screws in a femur using an awl.
- [0052] Figure 5C depicts the imaging of the screw holes and a nail in a first rotational orientation.
- [0053] Figure 5C' depicts the imaging of the same holes shown in Figure 5C with the nail at a slightly different rotational orientation.
- [0054] Figure 6A depicts a nail inserted in a fractured femur in accordance with the present invention.
- [0055] Figure 6B depicts a proximal end view of the nail shown in Figure 6A.
- [0056] Figure 6C depicts a side view of the proximal end of the nail depicted in Figure 6A.

[0057] Figure 6D depicts a screw suitable for use in locking the proximal end of the nail shown in Figure 6A.

[0058] Figure 6E depicts torquing grooves in the head of the screw shown in Figure 6D.

[0059] Figure 6E' depicts an alternative torquing groove in the head of the screw shown in Figure 6D.

[0060] Figure 7A depicts the distal end of the nail shown in Figure 6A.

[0061] Figure 7B depicts a side view of the distal end of the nail as shown in Figure 7A.

[0062] Figure 7C depicts a screw suitable for use in locking the distal end of the nail shown in Figure 7A.

[0063] Figure 7D depicts a torquing groove in the head of the screw shown in Figure 7C.

[0064] Figure 7D' depicts an alternative torquing groove in the head of the screw shown in Figure 7C.

[0065] Figure 8A depicts a cross-section of the nail shown in Figures 6A and 7A.

[0066] Figure 8B depicts a different cross-section of the nail shown in Figure 8A.

[0067] Figure 9A depicts a cross-section of a nail similar to that shown in Figure 8A formed of two separate members.

[0068] Figure 9B depicts a different cross-section of the nail shown in Figure 9A.

[0069] Figure 10 depicts a locking screw for locking a nail.

#### Best Mode for Carrying out the Invention

[0070] In accordance with the invention, and except as otherwise described below, the

preparation of the patient and the surgical incision are performed as described previously. A starting hole, as in conventional techniques, will be made in the greater trochanter, and a guide wire will be inserted through the greater trochanter, and into the intermedullary canal, stopping at the predetermined end of the distal femur. Once the wire has been seated properly, as confirmed by a fluoroscopy machine, reaming of the proximal end of the femur in the trochanter area will be performed with different size reamers. The proximal end of the greater trochanter can be reamed up to 17 millimeters. This size will vary depending upon the individual patient. That is, the reaming will be customized to accommodate the varied anatomy of individual patients.

**[0071]** Referring now to Figures 6A-6E', the nail 600 has a proximal end 602, with a diameter  $D_p$  which is larger by 2, 3 or 4 millimeters, or even more, than the diameter of the shaft portion 604 of the nail. The proximal end 602 will have a maximum diameter of 17 millimeters corresponding to the maximum diameter of the reamed hole. The diameter  $D_s$  of the shaft portion 604 of the nail 600 is in the range of 9-14 mms, and is selected by the surgeon based on the size of the intermedullary canal, as is well understood in the art.

**[0072]** After reaming is performed to accommodate the larger proximal end 602 of nail 600, the nail 600 is seated over a guide wire as previously described. More particularly, both a reaming and a non-ball tipped guide wire for placement of the nail, are utilized.

**[0073]** Once the nail 600 is seated, a fragment portion 652 of the greater trochanter 650

of the femur will be removed, without disturbing the attachments, to allow direct visualization of pre-drilled holes 606 in the proximal end 602 of the nail 600. These holes 606 are angled in the face 608 of the proximal end 602 of the nail 600. Because of the orientation of these holes, a guide wire can be used to determine whether the subsequently inserted attachment screws will exit from the nail 600 into the bone of the lesser trochanter 654 along centerline 608B or, if desired, the neck 656 and be seated in the subcapped area in the head 658 of the femur along centerline 608A.

**[0074]** The guide wires are necessary to ensure that the orientation, e.g. rotation, of the nail 600 is proper, so that the attachment screws will not exit the outer surface of neck 656 of the femur or the cortical outer surface of the lesser trochanter 654. This can be confirmed with anterior, posterior, lateral and even oblique images generated by a fluoroscopy machine.

**[0075]** Once the proper orientation of the nail 600 has been confirmed, the guide wire is removed. The pre-drilled holes 606 in the proximal end 602 of the nail 600 will now guide either hollow or solid screws into the lesser trochanter 654 or head 658 of the femur to complete the locking of the nail 600 at its proximal end 602 to the femur.

**[0076]** Upon completion of the seating of the nail 600, the trochanter fragment 652 can be resutured to the greater trochanter. This will ensure that the bone fragment 652 will reattached itself to the femur in time.

**[0077]** The screws 610 have capped heads 612 to prevent entry of scar tissue or healing bone into the holes 606. One or more grooves 614 or 614' are provided in the face 616 or 616' of the head 612 for a screwdriver, Allen wrench or other type torquing device.

**[0078]** It should be recognized that the pre-drilled holes 606 could, if desired, be provided to allow the screws to be seated in the lesser trochanter area 654 or the subcapped portion of the head 658, or both. In such case, the surgeon can decide to insert the screw along either centerline 608A or 608B on a case-by-case basis.

**[0079]** Because the proximal end of the femur is larger and much wider than the distal end, the proximal end 602 of the nail 600 is much wider than the distal end of the nail. Therefore, the proximal end 602 is able to accommodate one or more screws for seating in the subcapped area of the head 658 or into the lesser trochanter 654.

**[0080]** Referring now to Figures 7A and 7B, unlike conventional nails, the locking hole or holes 622, in the distal end 620 of the nail 600 are at the very end of the nail. This allows a widened portion 624 at the end 620 of the nail 600 to accommodate variable size holes 622. The hole size is varied based on the length L of the expanding distal end portion 624 of the nail 600.

**[0081]** For example, with an 11 mm nail, the distal end portion 220 can be wider by 1-2 millimeters than the shaft 604. Thus, the distal end portion 620 will have a widened portion

624 with a diameter  $D_d$  of 12-13 millimeters. If a 12 mm diameter nail is used, the expanded distal end portion 624, which accommodates the distal locking hole or holes 622, may be 13 millimeters or even up to 14 millimeters in diameter. The reaming to accommodate the widened distal end portion 624 will be performed by using a 13-16 mm diameter reamer. As is customary, a reamer is typically selected so as to form a nail hole, which is 1-2 millimeters larger than the nail diameter. Accordingly, in the case of the 11 mm nail, the distal portion 660 of the fractured femur could be reamed up to 13 mm, thereby providing a 2 mm increase in the reamed diameter to accommodate the 11 mm diameter nail shaft 604 and distal end portion 624 of the nail 600. For a 12 mm diameter nail, the expanded distal end portion 624 could be 13 mm or 14 mm in diameter. Reaming to 14 mm will accommodate the 13 mm, and most probably even the 14 mm diameter of the expanded distal end portion 624 of the nail 600. It should be noted however, that, regardless of the reamed diameter, if difficulty is encountered in inserting the nail, it is likely that the expanded distal end portion 624 is the cause of the difficulty. In such a case, the nail should be removed and further reaming should be performed up to another millimeter. Hence, if a 12 mm nail with a 14 mm diameter expanded distal end portion 624 is difficult to seat, then the reaming should proceed up to 15 mm. The additional 1 mm in the reamed diameter will not create a problem because the nail 600 locked proximally and distally with the screws. Therefore, with the enlarged reamed diameter the nail 600 can be easily seated and will firmly hold the fragments of the fractured femur in good position.

**[0082]** Figure 7B illustrates that the inner diameter  $D_{di}$  of the cortices, so to speak, of

the distal end 620 are preferably the same as the outer diameter  $D_s$  of the cortices of the shaft 604 of the nail 600. The distal end portion 620 of the nail 600 will have an aperture 626 or alternatively will be cannulated throughout to the far distal end, to accommodate an intermedullary guide wire. The distal locking screws 628 may be cortical held screws, having a head diameter to match the diameter of the distal hole or holes 622. The screws 628 engage both the near cortex and the far cortex of the distal portion of the femur. This engagement ensures firm fixation.

**[0083]** Once again, it is reemphasized that, at the distal end of the nail 600, the size of the holes 622 will be greater than the diameter of holes found in conventional nails. The increase in the diameter will be by an amount either exactly or substantially equal to the difference between the diameter  $D_s$  of the shaft 604 of the nail 600 and the diameter  $D_d$  of the expanded distal end portion 624, typically 2 millimeters. Furthermore, the diameter of the distal end 620 of the nail 600 will be a millimeter or more larger than that of a conventional nail.

**[0084]** The screws 628 are seated in the conventional manner. If necessary, a guide wire is inserted across the cortices from the near cortex and through the hole 622 of the distal end 620, engaging the far cortex of the femur. It is advisable, although not absolutely necessary, that the distal end 620 of the nail 600 accept at least two screws 628. Cannulated screws may be used to shorten the operative time, since such screws can be placed over the guide wires, and are therefore typically much easier to engage in the

holes. Needless to say, a cannulated drill bit would also be needed, if a guide wire is used to insert cannulated screws. The use of cannulated or solid screws will provide sufficient structural strength to prevent rotational or other malalignment.

**[0085]** The screws 628 have capped heads 630 to prevent entry of scar tissue or healing bone into the holes 622. As described above, the outer surface of the head is curved to match the curvature of the outer surface of the expanded distal end portion 624. As shown in Figures 7D and 7D', one or more grooves 632 or 632' are provided in the face 634 or 634' of the head 630 for a screw driver, Allen wrench or other torquing device.

**[0086]** Figure 8A depicts a cross-section of the nail described above with reference to Figures 6A and 7A. As shown, the proximal end of the nail is preferably curved approximately an angle of 20° to 30° off vertical. The nail also includes an aperture 800 in an upper portion of the proximal end of the nail directly above a threaded portion 810 formed along the inner diameter of the proximal end portion of the nail. A driver for use in implanting or extracting the nail is inserted through the aperture and torqued until locked by the threads 810. Thus, the aperture 800 and threads 810 will provide a positive lock between the nail and the driver to facilitate insertion of the nail into the reamed cavity and removal of the inserted nail from the reamed cavity by the surgeon. It will also be recognized that, if desired, an extraction awl can be utilized for removal. In such a case, the tip of the awl will be inserted through the aperture 800 but will not be locked by the threads 810. Rather, the hook at the end of the awl can be moved so as to bear against an

inner surface of the nail as it is pulled by the surgeon to thereby extract the nail from the reamed cavity.

**[0087]** Figure 8B depicts another cross-section of the nail shown in Figure 8A. As shown, the nail has secondary curvature of the proximal end. This curvature angles the proximal end in the range of 5° to 7°.

**[0088]** Figures 9A and 9B depict a cross-section of a nail similar to the nail shown in Figures 8A and 8B. However, the nail shown in Figures 9A and 9B is modular. More particularly, the nail is formed of two separate members, i.e. proximal end member 925 and distal end member 950. As shown, the proximal end member 925 and the distal end member 950 both include threaded portions in the area identified by reference numeral 940. In the case of proximal end member 925, the threaded portion 927 and area 940 includes treads on both the inner and outer diameter. The distal end portion 950 includes treads along its inner diameter in the area 940. The outer diameter treads 927 of the proximal end portion lock with the inner diameter treads 952 of the distal end portion to form the nail. A driver or extractor can then be inserted through the aperture 900 and torqued to lock to the inner diameter treads 927 of the proximal end portion 925 for installation and removal of the nail to or from the reamed cavity.

**[0089]** It should be noted that the modular configuration of the nail shown in Figures 9A and 9B allows a surgeon to utilize any desired number of proximal end portions with a

relatively small number of distal end portions to create a wide variety of nails having different proximal end orientations and lengths. The modular configuration also allows manufacturers to provide the modular components to form a vast array of different nails while needing to only maintain an inventory of a relatively small number different distal end portions. Potentially, the manufacturer could even limit itself to only one type distal end portion which can be utilized with any number of proximal end portions to form the desired nail.

**[0090]** Figure 10 depicts a screw particularly suitable for use in locking both the proximal and distal ends of the previously described nails. The screw shown in Figure 10 can also be beneficially utilized to lock conventional nails.

**[0091]** The size of the locking screws will typically be selected by the surgeon. The selected screws may be fully or partially threaded. Preferably, the screws will be 5.0, 6.0, 7.3, 16.0, or 32.0 mm in diameter. Beneficially, cannulated partially or fully threaded screw will be utilized to lock the nail to the bone. The same size screws are generally recommended for locking both the proximal and distal ends of the nail.

**[0092]** If cannulated screws are utilized, the screws can be guided by a guide wire inserted into the drilled screw holes.

**[0093]** As shown in Figure 10, beneficially a partially threaded cannulated screw 1000 is

utilized to lock both the proximal and distal ends of the nail. A groove 1010 is provided in the head 1005 of the screw to torque the screw 1000 such that the threads 1015 on the outer diameter of the screw 1000 engage the inner diameter of the drilled hole to lock the nail in place.

**[0094]** The screw 1000 includes inner diameter threads 1020 and 1025 for engaging a solid metal insert 1050. As shown, the insert 1050 includes a groove 1060 in the insert head 1055 for torquing the insert 1050. The insert 1050 includes outer threads 1065 and 1070 which engage with the threads 1020 and 1025 of the screw 1000 as the insert is torqued via groove 1060. The screw 1000, with the solid metal insert 1050 provides additional strength against breakage, while still allowing the use of guide wires for installation of the screw into the nail locking position.

**[0095]** It will also be recognized by those skilled in the art that, while the invention has been described above in terms of one or more preferred embodiments, it is not limited thereto. Various features and aspects of the above described invention may be used individually or jointly. Further, although the invention has been described in the context of its implementation in a particular environment and for particular purposes, e.g. orthopedics, those skilled in the art will recognize that its usefulness is not limited thereto and that the present invention can be beneficially utilized in any number of environments and implementations. Accordingly, the claims set forth below should be construed in view of the full breath and spirit of the invention as disclosed herein.